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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,318	03/12/2004	Birger Hjertman	320011.00504	6148
27160	7590	03/11/2005	EXAMINER	
KATTEN MUCHIN ZAVIS ROSENMAN 525 WEST MONROE STREET CHICAGO, IL 60661-3693			ROBERT, EDUARDO C	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/798,318	Applicant(s) HJERTMAN, BIRGER	
	Examiner Eduardo C. Robert	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/29/04</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Specification***

The continuing data at the beginning of the specification should be updated to reflect the current status of each application. Furthermore, applicant should amended the reference of PCT/SE96/01303 to state that application 09/060,052 is a 371 of PCT/SE96/01303 filed on 10/14/1996, which claims benefit of 60/005,775 filed on 10/20/1995.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 there exits an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "An injection device" with the injection cartridge, holder device, piston, piston rod, and control unit being only functionally recited, i.e. "for the administering of one or more injections from an injection cartridge which is arranged in a holder device and at its rear end is provided with a piston which by means of a piston rod may be displaced forwards, and wherein the readying of the device for the administering after the positioning of said cartridge, and the subsequent administering therefrom are

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controlled by an electronic control unit", thus indicating that the claim is directed to the subcombination, "An injection device". However, in lines 6-9, applicant positively recites the control unit, the piston rod, and the injection cartridge as part of the invention, i.e. "said control unit comprises a position sensor which emits signals which govern the control unit in such a way that during the readying of the device, forward movement of the piston rod is made possible only when the longitudinal axis of the injection cartridge is oriented in a predetermined direction", thus indicating that the combination, injection device and injection cartridge container arranged in a holder device and electronic control unit, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-6 will be considered as being drawn to the combination, injection device and injection cartridge arranged in a holder device and control unit.

Furthermore, in claim 1, line 2, "its rear end" is indefinite because it is unclear about which rear end applicant is taking about, e.g. the rear end of the injection cartridge, the rear end of the holder device, etc. In line 8, "the longitudinal axis" lacks a prior antecedent.

Claims 3, 5, and 6 are an improper dependent claim because they do not further limit the structure of parent claims 1 or 2 or 4, but rather merely recites a method step for readying the device. It is noted that the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

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In claim 7, line 4, "its" is indefinite because it unclear about what applicant is taking about, e.g. the device, the position sensor, etc. In line 6, "and/or" is indefinite because it is unclear what limitation such language places on the claimed subject matter.

In claim 16, line 2, "and/or" is indefinite because it is unclear what limitation such language places on the claimed subject matter.

In claim 19, line 2, "displacement" should be changed to -- displacing --.

In claim 20, line 3, "said means" is indefinite because it is unclear about what applicant is talking about, e.g. the displacing means, arming means, valve means, fluid control means.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,989,221. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims

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lies in the fact that the patent claims include more elements and is more specific. The invention of the patent claims is in effect and “species” of the “generic” invention of the application claims. It has been held that the generic invention is “anticipated” by the “species”. *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,709,416. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims lies in the fact that the patent claims include more elements and is more specific. The invention of the patent claims is in effect and “species” of the “generic” invention of the application claims. It has been held that the generic invention is “anticipated” by the “species”. *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 12, 13, 16, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ford et al. (U.S. Patent No. 5,681,285 cited by applicant)

Ford et al. disclose an injection device 10 comprising a syringe 20 having a container 28 for a preparation, an outlet, and displacing means, i.e. plunger 34 (see Figure 1). The device 10 further comprises a position sensor or mercury switch designed to emit a position signal indicative of the device orientation (see col. 9, lines 60 and 61) and a DC motor which activates the displacing means by a plunger clamp 32 (see col. 8, lines 27-59). The device 10 also has a control unit designed to receive the position signal and issue a control signal (see col. 9, lines 23-26 and lines 61-63).

Claims 1-3, as understood, 7, 8, 12-16, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Goethel (U.S. Patent No. 4,695,271 cited by applicant).

Goethel discloses an injection device 10 comprising an injection cartridge 22 arranged in a holder device 14. The cartridge 22 has a piston 26 which by means of a piston rod 29 may be displaced. The injection device further has a control unit 40 connected to a position sensor or mercury switch 48. The position sensor 48 determines the vertical position of the syringe cartridge 22 in the holder device. When the syringe cartridge is in the vertical position, the position sensor 38 sends a signal to the control unit 40 indicating that forward movement of the piston rod is possible (see col. 2, lines 30-55). The piston rod is not displaced forward until the control unit receives the positive

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signal from the position sensor. The movement of the piston rod is effected by means of an electrical motor 28 which is control by the control unit 40. It is noted that the control unit is designed to issue operation signals or control signals, i.e. signals design to prevent displacing of the piston rod, signals to allow displacing of the piston rod, etc. The piston rod incorporates an arming means, i.e. plunger 27, which mates with plunger 26.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, as understood, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goethel (U.S. Patent No. 4,695,271 cited by applicant) in view of Kapelowitz (U.S. Patent No. 3,680,558 cited by applicant).

Goethel discloses the claimed invention except for the injection cartridge being a multi-chamber cartridge. Kapelowitz discloses a multiple-chamber injection cartridge which can be used for the administration of incompatible medicaments to be mixed in the cartridge prior or during injection (see col. 2, lines 20-23 and Figure 4). It is noted that the injection cartridge has a movable piston separating the chambers and a by-pass section (see Figure 4). It would have been obvious to one skill in the art at the time the invention was made to construct the injection cartridge of the injection device of Goethel as a multiple-chamber injection cartridge in view of Kapelowitz, in order to administrate incompatible medicaments which will mix in the cartridge prior or during injection.



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Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goethel (U.S. Patent No. 4,695,271 cited by applicant) in view of Rondelet et al. (U.S. Patent 5,254,096 cited by applicant)

Goethel discloses the claimed invention except for one control signal being an alarm or instruction detectable by an operator. Rondelet, et al. teaches to construct a control unit of an injection device capable of issuing signals or instructions which will alert an user of the condition of the device, i.e. errors in the device (see abstract, lines 12-17 and col. 6, lines 22-33). It would have been obvious to one skill in the art at the time the invention was made to construct the control unit of Goethel being capable of issuing a signal which will alert the user of the condition of the device in view of Rondelet et al., so that the user could identify a problem or error very fast.

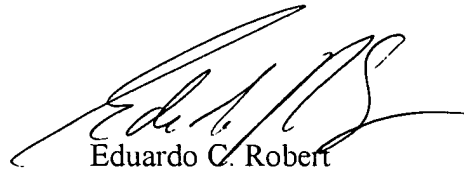
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 571-272-4719. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 571-273-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert  
Primary Examiner  
Art Unit 3732

E.C.R.